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UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
SHERR-UNA BOOKER, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* #1 TO EXCLUDE EVIDENCE OF RECOVERY FILTER COMPLICATIONS AND OTHER COMPLICATIONS THAT ARE NOT SUBSTANTIALLY SIMILAR** (The Honorable David G. Campbell) (Oral Argument Requested)

Plaintiff hereby responds in opposition to Defendants' Motion *in Limine* No. 1.

I. FACTUAL BACKGROUND

This case focuses on the design, manufacturing, testing, and marketing of an IVC filter submitted to the FDA on March 2, 2005 via the 510(k) process and represented as "the Recovery Filter System," K050558. Exhibit A. The filter's trade name changed to "G2 Filter System" at the time of clearance and marketing on August 29, 2005 only because concern existed that it would be mistaken as a retrievable filter; an indication the filter did not receive until July 2008. Exhibit B. The Recovery/G2 filter at issue in this case was predicated on the prior Recovery filter that had received FDA clearance first as a permanent filter and later as a retrievable filter. The content of the 510(k) application was not changed when the trade name changed from "Recovery" to "G2". In fact Bard

submitted another "Traditional" 510(k) for the same device at issue in this case after the March 2005 submission and still called it the "Recovery Filter System". Moreover, Bard's marketing employees considered the "G2" the same product as Recovery and an extension of the product line regardless of what its trade name became; plans were established for the "Recovery Road Show" to tell the "compelling story with the Recovery Filter" while referring to the G2. Exhibit C.

The substantial similarities between the predicate device Recovery filters and the "Recovery Filter" renamed "G2" (cleared in August 2005) that Plaintiff received, is easily observed through Bard's own representations to the FDA. Exhibit D is a chart comparing Bard's representations to the FDA when seeking clearance to market the device, and what Bard represents now in claiming that the devices are so radically different that evidence of complications with the Recovery filter is inadmissible. In its Motion, Bard ignores the similarities between the Recovery predicate device and the modified Recovery subject device (later renamed the G2) which were the basis for its claims to obtain "substantial equivalence" to market the product. Moreover, Bard emphasizes so-called "significant changes" it made to the Recovery/G2 device while it downplayed those differences in the 510k application: "The design, material, components, fundamental technology (mode of device function/operation) and intended use featured with the Recovery Filter System are substantially equivalent to those featured with the predecessor Recovery Filter System (reference K022236 and K031328) based on the design verification and validation information provided in ***Section IV***." Exhibit A at BPV-17-01-00125358 (emphasis added). Yet Section IV of Bard's 510(k) submission specifically refers to the design validation procedures used ***for the predicate Recovery device***, with the exception of what it describes as "[t]he only modifications to the filter design were the modified arms and hooks as described in the Comparison Summary section of this submission. All other aspects of the subject device filter and delivery system have been previously validated with the predicate device." Exhibit A at BPV-17-01-00125362-363.

For Bard to have obtained clearance to market based on a "substantial equivalence" determination by describing similarities and *lack of* differences between the subject device and its predicates, and now claim that incidences related to the predicate are substantially "dissimilar" and therefore inadmissible rings hollow in light of Bard's legally-required characterization of its devices outside the context of litigation. Allowing Bard to change its story for this litigation and exclude evidence of the Recovery filter predicate devices would result in irreversible prejudice to the Plaintiff. On the one hand, Bard relies on FDA clearance and communications during the 510(k) process to show that its filter design and actions were reasonable. Yet it simultaneously seeks to hide behind its back the other hand showing evidence of problems with the very device upon which this clearance was secured. This is not only unfair, but misleading. Further, hiding evidence of the Recovery's performance history—as tracked by Bard pursuant to its own internal protocols and regulatory requirements—robs Plaintiff and her experts of a critical comparison, which is particularly important given the fact that some failure rates increased rather than decreased with Bard's minimal design changes.[1] In addition to showing Bard's notice of the problems with its device, such comparative failure rate and adverse event evidence is relevant to Plaintiff's defective design claims and the issue of punitive damages since the evidence tends to suggest that only superficial changes to its early devices were made for marketing rather than performance reasons.[2]

II. ARGUMENT AND CITATION OF AUTHORITY

A. Other Adverse Events Associated With Bard's Retrievable Filters Are Admissible

[1] Plaintiffs' Omnibus Statement of Facts in Support of Their Response to Defendants' Motions for Summary Judgment in the Bellwether Cases (Doc. 8186) includes many examples of evidence where Bard was aware by 2005 that G2 did not have increased migration resistance over Recovery as advertised (¶69, ¶73, ¶79), G2 was inferior as to caudal migration (¶84), there is an expectation that a cleared device will be as safe as its predicate (¶16), it could have employed penetration limiters as early as the Recovery device (¶23), the G2 could not perform as well Recovery or Recovery's predicate (¶66).

[2] *See* Plaintiffs' Omnibus Statement of Facts in Support of Their Response to Defendants' Motions for Summary Judgment in the Bellwether Cases (Doc. 8186, ¶102). The Eclipse name change was merely to "break with the baggage associated with the previous versions [Recovery and G2]."

Existing cases do not address the unique situation involving the showing needed to allow admission of evidence concerning substantially similar "adverse events" (complaints) associated with one medical device that has been deemed substantially equivalent to another when seeking the right to market the product, and the complaints associated with the predicate device. Case law in the area of "other accidents" and "other similar incidents" is limited primarily to automotive defect claims and premises liability accident cases. Those claims are different and of little help here since the adverse events are collected and produced by Bard pursuant to its own policies and FDA regulations. Indeed, as the Court is aware, a manufacturer can only market the product when the comparison of the new device with its predicate results in a finding based on the manufacturer's representations that the device's designs are so similar that an accepted safety equivalence of one product essentially allows for the marketing of another. *See* 21 U.S.C. §360c(i)(1)(A). Thus, complaints like those associated with the Recovery filter do not present the same threat of confusion and undue prejudice that traditional other incident evidence can. Given this factor, Plaintiff submits that the admissibility of adverse event data should be subject merely to a traditional Rule 401/403 inquiry. Under such an inquiry, the evidence is not only extremely probative of several issues in the case (negligence, design defect, punitive damages, warnings, to include a few), but also not unduly prejudicial since it is based on Bard's own product performance and Bard and its experts are free to argue that the evidence should be given less weight because of different circumstances (which Plaintiff's experts will rebut).

Nevertheless, even assuming for the sake of argument that traditional "other similar incident" analysis from the Ninth Circuit governs this issue, the current state of the law where a party seeks to introduce other similar incidents to prove up negligence, design defect, or notice is based on whether those incidents are substantially similar to those associated with the product at issue. *Cooper v. Firestone Tire & Rubber Co*., 945 F.2d 1103, 1105 (9th Cir. 1991). Whether incidents are substantially similar for admissibility purposes depends on the theory of the case. *Younan v. Rolls–Royce Corp*., 2013 WL

1899919, at *9 (S.D. Cal. May 7, 2013) (quoting *Four Corners Helicopters, Inc. v. Turbomeca, S.A.*, 979 F.2d 1434, 1440 (10th Cir. 1992)). Where a party seeks admissibility of other incidents for the purpose of notice, the requirement is "less strict." *Pau v. Yosemite Park & Curry Co*., 928 F.2d 880, 889 (9th Cir. 1991). Customer reports, which are essentially what medical device complaints are, are admissible under the business records exception to the hearsay rule. *White v. Ford Motor Co*., 312 F.3d 998, 1009 (9th Cir. 2002*), opinion amended on denial of reh'g*, 335 F.3d 833 (9th Cir. 2003) (showing Ford had notice of rollaways and holding that the district court redacted reports of dissimilar rollaways that even if what customers reported was hearsay, it was harmless error). Dissimilarities that are minor or immaterial do not prevent admissibility. *White*, 312 F.3d at 1009 (9th Cir. 2002) (citing *Cooper*, 945 F.2d at 1105). "If products share the specific design features alleged to be defective, it may be that other differences between the products, such as tire size, are 'immaterial'." *Albee v. Cont'l Tire N. Am., Inc.*, 2010 WL 1729092, at *6 (E.D. Cal. Apr. 27, 2010) (quoting *White*, 312 F.3d at 1009). Moreover, where incidents are not identical, they can be substantially similar and therefore admissible to indicate the existence of a defect. *Four Corners Helicopters, Inc*., 979 F.2d, at 1440.

Bard now attempts to create substantial *differences* regarding its products in the face of having utilized a system (the 510(k) clearance process) based on showing substantial *similarities* and in fact "substantial equivalence" as to safety and effectiveness between the predicate a subject devices (*i.e.*, Recovery for G2, G2 for G2X/G2 Express, and G2 Express for Eclipse) to meet the clearance standard. 21 U.S.C. §360c(i)(1)(A).

"***Different Models"*** - In their Omnibus Statement of Facts in Support of Their Response to Defendants' Motions for Summary Judgment in the Bellwether Cases, Plaintiffs presented a broad foundation for the substantial similarities that exist as to the common design of the Recovery, G2, G2X/Express, and Eclipse filters share. (Doc. 8186). Bard also submitted each and every 510(k) submission for *all* of its filters as exhibits to its

Motion for Summary Judgment Related to Preemption[3]. This evidence shows that each of Bard's retrievable IVC filters was substantially equivalent and therefore substantially similar to the preceding filter with each adopting the design of the previous model in the Bard retrievable filter line. Exhibit E. Bard's own representations confirm the substantial similarities between Bard's designs of each of its retrievable filters based on its own representations in each 510(k):

Subject Device:	**Recovery (Renamed "G2") Permanent**	**Recovery G2 Retrievable**	**G2X/Express**	**Eclipse**
Predicate Device:	**Recovery**	**Recovery (Renamed G2) Permanent**	**Recovery G2 Retrievable**	**G2 Express**
Bard's Statement in 510(k) re: Design Similarity:	"The subject device description is identical to the Recovery Filter System description and indications. The modifications made to the Recovery Filter and delivery system are primarily dimensional. No material changes or additional components have been incorporated"[4]	"These devices are referenced as predicate devices because they are identical to the subject device …with the exception of the indications for use [retrievability]."[5]	"The subject device filter is identical to the predicate filter with the exception of the modified snare tip."[6]	"The primary modification form the predicate device…was an improvement of the surface finish…"[7]

The case law Bard cites is distinguishable. These are not heaters, cars, or ladders; these are 510(k)-cleared devices where Bard provided truth and accuracy statements

[3] *See* Exhibits C-1, C-6, C-14, C-43/C-54, C-102, C-104, and C-121 attached to the Declaration of Robert Carr (Doc. 5398), and Exhibits V-5, V-32, and V-66 attached to the Declaration of John VanVleet. (Doc. 5398).

[4] See Exhibit C-43 attached to Declaration of Robert Carr (Doc. 5398), at BPV-17-01-00125354.

[5] *See* Exhibit C-102 attached to Declaration of Robert Carr (Doc. 5398), at BPV-17-01-00123664.

[6] *See* Exhibit C-104 attached to Declaration of Robert Carr (Doc. 5398), at BPV-17-01-00130551-552.

[7] *See* Exhibit C-121 attached to Declaration of Robert Carr (Doc. 5398), at BPV-17-01-00117000

attesting to lack of differences between each model and each predicate without breaking the chain in order to represent comparative safety and efficacy.

"Different Alleged Injuries/Complications" – None of the device failures/complaints Bard recorded in the usual course of business that Plaintiff seeks to use are different from those that Ms. Booker experienced: tilt, perforation, fracture (often reported to FDA as "detachments"), and migration. *See* Exhibit F, Plaintiff's Summary Complication Chart. The chart attached as Exhibit E was compiled based on complaint data directly from Bard's complaint database produced to Plaintiff and on which Plaintiff intends to rely on at trial likely in the form of a summary chart in compliance with Federal Rule of Evidence 1006.[8] The incidents do not deviate from injuries Ms. Booker suffered.[9] Given these similarities, Bard's reliance on *Ramirez v. E.I. Dupont de Nemours and Co*., 2010 WL 3467655 (M.D. Fla. 2010), is misplaced. *Ramirez* dealt with the different applications, dosages, protective equipment usage, and chemical mixtures of a fungicide applied to crops outdoors, not a medical device with the same usage, indications, implant method, location and verified submission of similarities in design between it and a predecessor product allowing for its market release.

"Different Parts of the Same Model of Product" – Bard likens its IVC filters to a ladder in order to support its claims that different parts of the same model product can be defective and therefore not substantially similar to other failures. *Hamatie v. Louisville*

[8] To the extent Bard objects to the use of a summary chart at trial like the one attached, or that a hearing would be required on this matter to evaluate substantial similarities beyond the foundation already before this Court in this motion and Plaintiff's Opposition to Bard's Motion for Partial Summary Judgment (Doc. 7369) (partially referenced in the Court's Order dated November 22, 2017), Plaintiff requests that the Court schedule a brief evidentiary hearing before the start of trial so that these important issues can be promptly and fairly addressed without using any trial time.

[9] Plaintiff's expert interventional radiologist testified Ms. Booker experienced: caudal migration of the filter, migration of fractured strut to the heart, tilt, perforation, and penetration to outer lying organs. Exhibit G, Deposition Testimony of Darren Hurst, July 21, 2017, at 166:7-169:3; 172:7-15. Moreover, Bard suggests Ms. Booker's surgery was minimally invasive, yet she underwent open heart surgery. *See* Plaintiff Sherr-Una Booker' Supplement to the Plaintiffs' Omnibus Separate Statement of Facts in Support of Their Response to Defendants' Motion for Partial Summary Judgment, at ¶330. (Doc. 8171).

Ladder, Inc., 2007 WL 7626033, at *1 (M.D. Fla. 2007). Yet Bard admits in its 510(k) applications that the design of its filters are predicated on the last and do not deviate significantly if at all from the previous design or raw material. If Bard's argument is that different pieces of the same raw material somehow cause dissimilar events of fracture when those filters are almost identically designed and using the same raw materials, such distinctions would constitute "minor or immaterial" differences that do not prevent admissibility. *White*, 312 F.3d at 1009.

"Different Medical Courses" – Bard does not elaborate on this alleged basis for rendering other complications inadmissible. Plaintiff submits that medical treatment related to other complications is not relevant to the design defects alleged or the existence of these complaints as notice to Bard of the defect. Bard's argument fails for two reasons. The "different medical course" explanation of failures is Bard's defense. But Plaintiff's experts opine that the failures result from the filters' defective design, which permits tilting and subsequent migration, fracture and often perforation.[10] Excluding adverse event evidence of the Recovery filter would unfairly weight Bard's defense and undermine Plaintiff's experts. Moreover, the critical inquiry as to substantial similarity is not the environment of the failure but, rather, whether the failure was the result of the same design defect. *See, e.g.*, *Trevizo v. Astec Indus., Inc.*, 751 P.2d 980, 982 (Ariz. Ct. App. 1987) ("That the overheating [of the allegedly defective product] came about in this case from running with the failed wheel bearing [rather than from a different source] is immaterial. The injury resulted from the same design defect, and running with a defective bearing is neither unforeseeable nor extraordinary so as to excuse *Astec*."). Here, the adverse events all relate to the same central design defects and, as in *Trevizo*, differences in patients' medical courses are "neither unforeseeable nor extraordinary" to excuse Bard.

"Different conditions"- Bard is less clear as to what different conditions would apply under these circumstances. As stated above, a "substantially similar" argument is

[10] Exhibit H, Deposition Testimony of Dr. Robert McMeeking, July 6, 2017, at 22:17-23:28, 32:6 – 21; 32:22 – 33:8.

usually made to exclude evidence of automotive accidents, as well as other products not subject to representations regarding identical indications for use. Bard's reliance on automobile crash cases explains nothing about what different conditions it alleges would make other adverse events so dissimilar from those suffered by Ms. Booker. And, as set forth above, the different conditions are not relevant so long as the adverse events result from the same design defects, which Plaintiff's experts contend they do.

Cephalad vs. Caudal Migrations – Bard claims that migrations that are not caudal migrations are not admissible. Def. Mot. at 6. However, Bard took the exact opposite stance during the tracking and trending of these adverse events at the time the G2 was on the market. In early February 2006, only a few months after the G2 was cleared to market, Bard's Health Hazard Evaluation (HHE) combined caudal (9) and cephalad (1) migrations to a clean number of ten (10) when comparing the problem to competitive products in the literature. Exhibit I. It is disingenuous for Bard to now separate these out as substantially dissimilar when although it identified the difference in numbers, it essentially combined the two as the same for purposes of evaluating the safety if its product.[11] Also, Bard never made a distinction between cephalad and caudal migrations when reporting migrations to the FDA. See Exhibit F.

B. Evidence of Failures Associated With Recovery, G2, G2X/G2 Express and Eclipse Filters Are all Relevant to Prove Notice of Defect

Plaintiffs submit that any incidence of filter migration, tilt, fracture, and perforation is admissible to show notice of defect to Bard even if it occurred in devices other than the Recovery and G2 filters. First, Bard often relied on other devices including Recovery to determine the G2's safety profile including Recovery and G2X – they trended them together in order to determine performance, belying Bard's claim of dissimilarity. Exhibit

[11] In evaluating the problem, Bard combined both cephalad and caudal migration complaints in early 2006 and documented: "the literature reveals that the reported rates of filter migration and associated hazards for the G2 filter are not inconsistent with rates published in the literature for other filters. However, the cases reported in the literature have not been frequently associated with significant caudal movement . . . ." Exhibit I at BPVEFILTER-01-00008357.

J at BPVE-01-01239757-774. Ms. Booker did not receive her filter until 2007, yet her filter was not removed until 2014. Adverse events being reported to Bard of fracture, migration, tilt, and perforation associated with Bard's filters that had been deemed substantially equivalent to each other, where Bard attested to their near identical designs and minimal modifications certainly should be included as evidence of notice. Plaintiff has also provided foundation in its Omnibus Statement of Facts (Doc. 8186) and the chart attached as Exhibit E.

Also, Bard consistently claims it "warned" of the complications in the IFU. ***It did not***. Neither the Recovery nor the G2 filters' IFUs contain ***warnings*** about long-term risks of migration, fracture, or perforation. The IFUs contain language about failure modes ***related to the implantation process*** but do not warn about these complications post-implantation. And, Bard's IFUs only indicate migration, fracture and perforation separate from the implantation process as "Potential Complications." (Doc. 7457-1). Even if it did, the point of notice is so that the Defendant can make changes to its design or warnings; adequacy of a warning is for the jury to determine therefore the amount, severity and characterization of the kind of notice Bard had been receiving is relevant and complaints associated with the G2's predicate device are admissible.

C. Substantial Equivalence v. Substantial Similarity

The Court has observed, in its Order denying Defendants Motion for Summary Judgment on Plaintiff's punitive damages claim, that there is substantial similarity between the Recovery and G2 lines of filters. 2017 WL 5625548, at *11 (D. Ariz. 2017). Bard seeks to avoid this recognition by arguing that "substantial equivalence" is not tantamount to "substantial similarity" and affixes drawings with no context as an exhibit. This argument elevates form over substance. The FDA submission represents (with attendant attestations that the submissions are true and accurate) that the G2 device is similar in all material ways to its predicate Recovery filter, and that the later G2 filters (G2X/Express and Eclipse) are similar to the G2. Bard highlights design adjustments it

previously attested were minimal. In other words, the devices suffered from the same design defects and are therefore substantially similar.

For these reasons, evidence concerning Recovery filter complications and other complications subject to Defendants' Motion *in Limine* No. 1 should be denied.

RESPECTFULLY SUBMITTED this 9th day of February, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of February, 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti